

and develop new and innovative approaches to reduce welfare dependency, as well as the Tribal Temporary Assistance for Needy Families (TANF) and Job Opportunities and Basic Skills Training (JOBS) programs.

2. KG.10 Organization. Delete this section in its entirety and replace it with the following:

KG.10 Organization. The Office of Community Services is headed by a Director who reports directly to the Assistant Secretary for Children and Families and consists of:

Office of the Director (KGA)

Division of State Assistance (KGB)

Division of Community Discretionary Programs (KGC)

Division of Community Demonstration Programs (KGD)

Division of Energy Assistance (KGE)

Division of Tribal Services (KGF)

3. KG.20 Functions. Add the following Paragraph F:

F. Division of Tribal Services is responsible for assisting in implementation and coordination of ongoing consultation with tribal governments and, where appropriate, state and federal agencies regarding issues relating to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, P.L. 104-193 (the Act) and related legislation. It is also responsible for development of regulations and guidelines and for providing leadership, policy direction, technical assistance and coordination of tribal services programs. Performs inter and intra-agency liaison functions in all areas such as Child Support Enforcement, Child Care, Child Welfare, Foster Care, Low Income Home Energy Assistance, and Family Violence to promote family stability, economic security, responsibility and self-support for Native Americans. It is responsible for conducting program reviews to ensure compliance with the Act, regulations and policy directives. It is responsible for activities related to tribal data collection reporting requirements relating to the programs.

Dated: February 21, 1997.

Olivia A. Golden,

Principal Deputy Assistant Secretary for Children and Families.

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Food and Drug Administration

Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held on April 8, 1997.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee continues CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and

Ombudsman. Meetings will ordinarily be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. Publication of any meeting cancellation will be made only as time permits.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division within CBER will notify the sponsor.

Dated: February 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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Health Care Financing Administration

[Document Identifier: HCFA-855]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to